

Notice of Allowability

Application No.

10/561,055

Examiner

MLouisa Lao

Applicant(s)

HOLMES ET AL.

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/2/2007.
2. ☒ The allowed claim(s) is/are 2 and 6-8.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 12/16/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 4/17/2007.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
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Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2 and 6-8, drawn to a compound with formula (Ia) and the method of making said compound, as recited; and a pharmaceutical composition comprising a compound of formula (Ia), pharmaceutically acceptable carriers or diluents, or anti-infective agents.

Group II, claim(s) 4 drawn to a method for treatment of a human or animal with an autoimmune disorder or an inflammatory condition, where said disorders are recited, therein.

As per the telephone interview with Ms. Hsu, *Esq.*, Applicants are electing Group I (claims 2 and 7) with traverse, thus reserving the right to pursue the other invention of this application at a later date. Attorney agreed to the cancellation of claim 4, as drawn to non-elected invention.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Grace Hsu, *Esq.* on 4/17/07.

The application has been amended as follows:

IN THE CLAIMS:

Please cancel CLAIM 4.

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In CLAIM 6, please add "and" before "pharmaceutically acceptable carriers or diluents".

Please delete the phrase, "*and optionally one or more other therapeutic agents selected from anti-inflammatory agents, NSAIDS, beta adrenergic agents,*"

In CLAIM 8, please re-word the claim to recite:

The pharmaceutical composition according to claim 6 further comprising one or more therapeutic agents, selected from anti-inflammatory agents, NSAIDS, beta-adrenergic agents and anti-infective agents, wherein:

the anti-inflammatory agents are selected from corticosteroids selected from fluticasone propionate, beclomethasone dipropionate, mometasone furoate, triamcinolone acetonide or budesonide);

the NSAIDs are selected from sodium cromoglycate, nedocromil sodium, PDE-4 inhibitors, leukotriene antagonists, CCR-3 antagonists, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists and adenosine 2a agonists;

the beta adrenergic agents are selected from salmeterol, salbutamol, formoterol, fenoterol or terbutaline and salts thereof; or

the anti-infective agents are selected from antibiotics or antivirals.

Response to Arguments

3. Applicant's arguments, see pages 6-8 under REMARKS, filed 3/2/07, with respect to rejection under 35 U.S.C. § 112, 1st and 2nd ¶'s of claims 1 and 4-7 have been fully considered and are persuasive.

Allowance

4. The following is an examiner's statement of reasons for allowance of the claims 2 and 8, as amended:

The prior art, such as EP606046, JP9104672 (equivalent to EP757984), JP11236369 and illustratively by Robinson et al. (WO 96/27583, WO '583) teaches arylsulfonylamino hydroxamic acid derivatives but not arylglycine derivatives, which make the latter structurally

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different compounds exhibiting variant properties from the WO`583 art. The process for the step-wise preparation of compounds of formula (Ia), i.e. N-arylglycine derivatives and related compounds, as recited in the claims, as amended, has not been suggested or disclosed in prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, Ph.D. whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Fridays from 8:30am to 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

`mll 04172007
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